PATENT Serial No. 10/524,316 02839/46401

## REMARKS

Claims 2, 3, 5, 6, 8, and 11-24 are pending in the present application.

## Rejection of Claims Under 35 U.S.C. 102 by Fukara

Claims 2, 6, 11-13 and 17 stand rejected as being allegedly anticipated by Fukara et al. (Prog. Neuro-Psychopharmacol. & Biol Psychiat., 2004, 24, 1357-1368) ("Fukara"). Applicants traverse this rejection.

The above-referenced claims recite providing analgesia to a newborn or fetal subject in need thereof. Previously, Applicants argued that the patient population in Fukara is not in need of analgesia. In this Office Action, the Examiner states that Fukara describes the homogenization of rat forebrains and that "the fetal and neonatal rats were in need of analgesia before having their brains homogenized. Clearly, a subject about to have their bains homogenized is in need of analgesia." (See Office Action page 3). What the Examiner is missing is that these rats would have been euthanized prior to having their brains homogenized for further analysis and thus would not be in need of analgesia. This is supported by the attached paper (Pfenninger et al, 1983) which is referenced in the Ellis et al paper, which is referenced by Fukara in the section describing the preparation of isolated growth cone particle. (See page 1359: Preparation of Isolated Growth Cone Particles (IGCs). The Pfenninger paper describes the dissection methods used in Fukara and no analgesic is provided to the rats. This makes sense since dead rats are not in need of analgesia. Specifically, the Pfenninger paper states that the dissection of the fetuses was carried out on ice or at 4°C. (See Fractionation Protocols, last sentence, first paragraph, page 582). Effectively, this is a method of euthanasia and at 4°C on ice there would be no life. The fact that rats would be killed prior to the culture procedures described in Fukara and referenced by the Examiner is also supported by the attached declaration of Nicholas Franks.

For at least these reasons, Applicants submit that claims 11 and 12 (and all claims that depend therefrom) are not anticipated by Fukara and Applicants request withdrawal of this rejection.

## Rejection of Claims Under 35 U.S.C. 102 by Lane

Claims 12, 17 and 21 stand rejected as being allegedly anticipated by Lane et al. (Science 190, 210(4472), 899-901) ("Lane"). Applicants traverse this rejection.

In the previous response, Applicants argued that Lane does not describe fetal subjects in need of analgesia. In this Office Action, the Examiner asserts that "Lane examined macroscopic anomalies in the fetal rats... Therefore, the fetal rats about to be experimented upon were in need of analgesia before undergoing these procedures." Applicants disagree with this assessment. As explained in the attached declaration of Mervyn Maze, the macroscopic organ anomalies described in Lane (encephalocele, hydrocephalus, anophthalmia, microphthalmia, eleft lip/palate, gastroschisis, gonadal agenesis, undescended testis, and shortened limbs) are diagnosed in rats by simple visual inspection. As such, these abnormalties could be detected without any invasive or otherwise painful procedure requiring an analgesic. Accordingly, Applicants again submit that Lane does not describe fetal subjects in need of analgesia.

For at least these reasons, Applicants submit that claim 12 (and all claims that depend therefrom) are not anticipated by Lane and Applicants request withdrawal of this rejection.

## Rejection of Claims Under 35 U.S.C. 103 by Fukara in view of Georgieff, Fishman, Ohashi and Franks

Claims 2, 3, 5, 6, 8 and 11-24 stand rejected as being allegedly rendered obvious by Fukara in view of U.S. Patent No. 6,197,323 to Georgieff ("Georgieff"), U.S. Patent No. 5,099,834 to Fishman ("Fishman"), Anesthesiology 96 A1291 (2002) to Ohashi ("Ohashi") and with respect to claims 5 and 24, U.S. Patent No. 6,274,633 to Franks ("Franks"). Applicants traverse this rejection.

As Applicants state above, Fukara does not describe administering xenon to a newborn or fetal subject in need of analgesia. Further, neither Georgieff, Fishman nor Franks describe this subject matter. Georgieff is directed to a liquid xenon emulsion that can be used as an anesthetic (See Abstract). Although Georgieff mentions that xenon has an analgesic action, there is no indication of using xenon as an analgesic in a fetal or newborn subject in need of analgesia. With respect to Fishman, this reference does not cure the deficiencies of Georgieff as this

PATENT Serial No. 10/524,316

02839/46401

reference does not describe using xenon to provide analgesia to a newborn or fetal subject in

need thereof. Rather, Fishman mentions using xenon as an anesthetic throughout (See e.g.,

Abstract; col. 2, lines 54-55; col. 4, lines 28-30; and col. 5, lines 37-43). With respect to Ohashi, this reference is not prior art as established by Applicants in their response of September 14.

2007. Regarding Franks, this reference describes using xenon as an NMDA antagonist and does

not describe using xenon as an analgesic agent in newborns and fetal subjects in need thereof.

For at least these reasons, Applicants submit that the above-referenced claims are not rendered

obvious by Fukara, Georgieff, Fishman, or Franks either alone or in combination and Applicants

request withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Denosit Account No. 11-0600.

Respectfully submitted, KENYON & KENYON LLP

Dated:	January 29, 2009	By:	/Zeba Ali/	
_		•	Zeba Ali	
			(Reg. No. 51,392)	

1500 K Street, N.W. Suite 700

Washington, D.C. 20005 Tel: (202) 220-4200 Fax: (202) 220-4201

NY01 1665632 v1